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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/570,043	03/01/2006	Martin Fussenegger	2006-0153A	6327

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WASHINGTON, DC 20006-1021

EXAMINER

LEAVITT, MARIA GOMEZ

ART UNIT	PAPER NUMBER
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1633

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12/19/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/570,043		FUSSENEGGER ET AL.	
	Examiner		Art Unit	
	Maria Leavitt		1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

- I. Claims 1-9, a **mammalian cell** comprising a nucleic which modulates transcription of an operator site (OP)- containing promoter in response to liquid or gaseous compounds a promoter operatively linked to the OP specific for binding RTF and a nucleic acid molecule encoding the desired protein functionally linked to said promoter.
- III. Claims 10-24 to a **method for adjusting** the expression level of a desired protein in a mammalian cell, said cell comprising a responsive transcription factor (FRT) which modulates transcription of an operator site (OP)- containing promoter in response to liquid or gaseous compounds, a promoter operatively linked to the OP specific for binding RTF
- IIII. Claims 25-27 to an **isolated nucleic acid** comprising a responsive transcription factor (FRT) linked to a promoter useful for expression of RTF.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical reasons:

37 CFR 1.475 (c) states:

“If an application contains to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present”

37 CFR 1.475 (d) also states:

“If multiple products, processes of manufacture, or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT article 17(3)(a) and 1.476(c)”.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical reasons: the technical feature linking groups I-III appears to be that they all relate to mammalian cells useful for regulated gene expression in response to compounds being gaseous or liquid at the cultivation temperature of said mammalian cell and to methods for producing proteins in mammalian cells in a regulated way in response to inducing gaseous or liquid compounds and to isolated nucleic acids useful for the construction of said cells. However, prior art has taught that acetaldehyde, the major active metabolite of alcohol, induces the activation of hepatic stellate cells (HSC) by activating endogenous mammalian promoter for transforming growth factor β (TGF- β), which leads to production of alpha (I) collagen gene expression in cultured HSC and hepatic fibrogenesis (Chen Biochem J. 2002 Dec 15;368 :683-93). Therefore, the technical feature linking the invention of groups I-III does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over prior art for the reasons set forth above.

The inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical reasons:

Inventions of Groups I-III are drawn to materially different and distinct inventive concepts, having different chemical structures, physical properties and biological functions. Inventions of **Group I drawn to a cell** are structurally and functionally different from inventions of **Group II drawn to a method** for producing proteins in mammalian cells in a regulated way in response to inducing gaseous or liquid compounds and structurally and functionally different from inventions of Group III drawn to an isolated nucleic acid. For example, inventions of Group II require administration of a test compound to a mammalian cell for adjusting the expression of a desired protein which step is not required by the cell or nucleic acid of Groups I or III, respectively. Because these inventions are distinct for the reasons given above, and are separately classified and searched, it would be unduly burdensome for the examiner to search and examine all of the subject matter being sought in the presently pending claims, and thus, restriction for examination purposes as indicated is proper.

Species restriction

Should Groups **I or II** be elected, a species restriction is further required under 35 U.S.C. 121 and 372, wherein a species election(s) must correspond to an elected group as indicated above.

1) Binding of the RTF to OP-containing promoters in response to the following conditions as recited in claims 3 and 4:

Gaseous and Liquid

The species are independent or distinct because there are **conditions** having different chemical structures, physical properties, and biological functions. Thus, the combined features

of a particular species, distinct structurally and functionally, would not necessarily overlap with one another when a prior art search is conducted.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 10 and 17 are generic.

2) A genus of proteins as recited in claims 11 and 18, selected from one of the following molecules:

SEAP, a fluorescent protein, human growth hormone, alpha-interferon, beta-interferon, gamma-interferon, insulin, erythropoietin, tissue plasminogen activator, DNase, a monoclonal antibody, Factor VII, Factor VII, HAS, IL-2, glucagons, EGF, GCSF, GMCSF, thrombopoietin, gp160, HbSAg, a protein encoded by a tumor suppressor gene, and a protein encoded by a gene interfering with absorption, distribution, metabolism and excretion of compounds contained in tobacco smoke

The species are independent or distinct because there are **proteins** having different chemical structures, physical properties, and biological functions as the result of being encoded by different genes. Thus, the combined features of a particular species, distinct structurally and functionally, would not necessarily overlap with one another when a prior art search is conducted.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 10 and 17 are generic.

3) A genus of compounds as recited in claims 12-14, 21-23 selected from one of the following molecules:

ethanol, methylamine, ethylamine, n-propylamine, n-butylamine, n-pentylamine, n-hexylamine, benzylamine, 2- butanone, ethanol, n-propanol, n-butanol, 2-propanol, 2-butanol, 2-methylbutyraldehyde, acetaldehyde, propanal, acetone, 2-butanone, 2-pentanone, 3-pentanone, cyclohexanone, glycoaldehyde, glyoxal, glyoxylate, ethylene glycol, ethanolamine, ethyl acetate, ethyl ether, and dicyclopropylketone, compounds that are metabolized in situ to said members of the group

The species are independent or distinct because there are **compounds** having different chemical structures, physical properties, and biological functions. Thus, the combined features of a particular species, distinct structurally and functionally, would not necessarily overlap with one another when a prior art search is conducted.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 10 and 17 are generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and identification of the claims encompassing the elected species, including any

claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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